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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,559	10/24/2005	John P. Wikswo	14506-48686	9529
24728 7590 12/12/2007 MORRIS MANNING MARTIN LLP 3343 PEACHTREE ROAD, NE 1600 ATLANTA FINANCIAL CENTER ATLANTA, GA 30326			EXAMINER LAM, ANN Y	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 12/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/525,559	Applicant(s) WIKSWO ET AL.	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 44-64 is/are pending in the application.
4a) Of the above claim(s) 1-41 and 50-57 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44, 46-49 is/are allowed.
- 6) ☒ Claim(s) 45 and 58-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17:2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>200712</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/3/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45 and 59-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Feder et al., 4,201,845.

Feder et al. teach a device comprising two parts (12 and 13) of a housing (11) secured together to define a chamber (23) within the housing (col. 3, line 13-18) and including a lower filter (40) which serves to distribute the upward fluid flow, and upper filter (41) which prevent cells from passing through the outlet port (col. 6, lines 1-8.) Part (12) is equivalent to Applicant's claimed first substrate, and the upper filter (41) which prevents cells from passing through is equivalent to Applicant's claimed confining means. The Feder et al. device also comprises inlets (26 and 27) and outlet 28) (see fig. 2). Inlets (26 and 27) comprise ports (openings) and thus are equivalent to Applicant's claimed inlet port and first connection channel, and first alternate port and third connection channel, respectively. Outlet port (28) is equivalent to Applicant's claimed outlet port and second connection channel.

As to claim 59, part (13) is equivalent to Applicant's claimed second substrate sized such that when the second substrate is received by the first substrate, the chamber is covered.

As to claim 60, element (37) is a supporting member outside the confined region of the chamber for supporting the second substrate (see figure 2).

As to claim 61, the device comprises a lip on the inside of element (12) which is inside the confined region of the chamber and supports the second substrate (13), see fig. 2 and also figure 3).

As to claim 62, a stream of substance is capable of being controlled as to provide a gradient to the channel, since the flow of fluid introduced can be controlled. It is noted that claim 62 claims a device rather than a method claim. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Likewise, as to claims 63 and 64, the stream of substance, or chemokine, or substance affecting the growth of biological cells, is not recited as part of the claimed device but is recited as part of the intended use of the device. The Feder et al. device is capable of allowing chemokine or a substance affecting the growth of biological cells to flow through the device. This is also shown in column 6, line 31, describing a culture medium inlet tube.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feder et al., 4,201,845.

Feder et al. disclose the invention substantially as claimed except for the first substrate being fabricated from glass or a polymer. Feder et al. describes the first substrate structure (12) (col. 3, line 19) does not mention what material forms the first substrate. However, glass or a polymer would have been obvious to the skilled artisan because Feder et al. disclose in the background that glass or plastic are known to be used for culturing cells (col. 1, lines 18-22), and also another part of the disclosed device may be made of a polymer. Thus, it would have been predictable to the skilled artisan that glass or plastic are compatible materials that may be used to form the structure (12) generally disclosed by Feder et al.

Allowable Subject Matter

Claims 44 and 46-49 are allowed.

Response to Arguments

Applicant's arguments filed September 29, 2007 have been fully considered.

In response to the 112, second paragraph rejection of claim 45, Applicant has deleted the language "for allowing seed biological cells to perfuse only outside the confined region in the chamber". By deleting this limitation, the claim is rendered broader and reads on the newly cited prior art as discussed above. Examiner placed a telephone call to Applicant's attorney, Tim Xia, to discuss claim 45. Examiner stated that new art will be cited against amended claim 45 because it is now broader than the previously submitted claim 45. A discussion of the 112, second paragraph made in the previous Office action was also made. Examiner explained that the 112, second paragraph rejection made in the previous Office action relates to whether the "biological cells" in the previously submitted claim 42, line 14, from which the previously submitted claim 45 depends, is distinguishable from "seed biological cells". It appears that Applicant intends for claim 45 to mean that the confined region allows seed biological cells but not larger biological cells to perfuse only outside the confined region, but this was not clear in the language of previously submitted claim 45. It is also not clear as to what Applicant means by "seed biological cells" and clarification as to its meaning is requested. Applicant's attorney stated that the skilled artisan would understand what "seed biological cells" mean and that Applicant's attorney can cite articles to show this.

As stated in the telephone interview, as a courtesy, the present Office action is made non-final to allow Applicant an opportunity to clarify claim 45 if Applicant wishes to reinstate limitations regarding "seed biological cells".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ann Y. Lam

Primary Patent Examiner